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10/803,329

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Anna N. Yaroslavsky

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EXAMINER

KISH, JAMES M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,329	Applicant(s) YAROSLAVSKY ET AL.	
	Examiner JAMES KISH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23, 25-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23, 25-28 and 30-35 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 35 is objected to because of the following informalities:

Claim 35 is stated as being "previously presented". This claim should have been presented as "New." Furthermore, in the Applicant's Remarks dated March 21, 2008, the Applicant states that claims 18-34 are pending in this application. Nonetheless, the merits of claim 35 have been addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23, 25, 32-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al. (US Patent No. 5,847,394) in view of Groner et al. (US Patent No. 5,983,120). Alfano'394 discloses a method and apparatus for imaging objects based upon the polarization of light. Preferably, the pulse of illuminating light is polarized. Where, for example, the pulse of illuminating light is linearly polarized, the pair of

complementary polarization components are preferably the parallel and perpendicular components to the polarized illuminating light, and the image may be formed by subtracting the perpendicular from the parallel component. See column 7, lines 25-30 for specific wavelengths used for the invention. Also, Alfano'394 is based, in part, on the discovery that one can image a turbid medium at various depths thereof by illuminating the turbid medium with light pulses of different wavelengths (column 4, lines 15-53). However, the final step of subtracting data from separate wavelengths is missing from Alfano'394. Groner teaches reflected imaging used to perform non-invasive, in vivo analysis of a subject's vascular system. Groner states that a correction function normalizes raw (i.e., uncorrected) reflected images with respect to the image background. One such correction function utilizes bi-chromatic correction in which two wavelengths are selected. By subtracting the data of a first wavelength from that of a second wavelength, all parameters that affect both wavelengths in the same manner cancel out (column 9, line 58 through column 10, line 9), leaving only the data that differs in the two wavelengths (i.e., the data gathered at the further depth penetration). In as much as Groner's described embodiment is for imaging of blood, hemoglobin is used as a natural contrast agent. One wavelength is chosen such that it lies at an absorbing wavelength of hemoglobin. A second wavelength is referred to as a "blank", in that it should be a non-absorbing wavelength for hemoglobin. Two such wavelengths described by Groner are 550 nm and 650 nm (column 12, lines 15-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to subtract data received by two different wavelengths, as taught by Groner,

in the system of Alfano'394 in order to view acquire image with better optical image quality and visibility of object features (Alfano'394: column 6, lines 66-67) while correcting the image with respect to the background (Groner: column 10, line 1).

Regarding claim 25, as taught by Alfano and Groner, illuminating turbid medium at various depths requires utilizing light pulses of different wavelengths. This is also described within the claim itself. Therefore, this claim is an intended use. Alfano and Groner are capable of performing this function depending on the wavelength and tissue region used.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner et al, and further in view of Kaufman et al. (US Patent No. 5,971,767). Alfano'394 in combination with Groner is previously described. However, these references do not discuss creating a three-dimensional image. Kaufman states that three dimensional images can be formed by stacking two-dimensional pictures produced from scanning machines. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a three-dimensional image, as taught by Kaufman, using the methods of Alfano and Groner, because visualizing an organ in three-dimensional space would be beneficial due to its lack of physical intrusion and the ease of data manipulation (column 1, lines 48-51).

Claims 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner et al., and further in view of either Eckhouse et

al. (US Patent No. 5,836,999) or Khalil et al. (US Patent No. 6,615,061). Alfano'394 in combination with Groner is previously described. However, neither of these references discuss a depth estimation. Khalil teaches that the penetration depth is the reciprocal of the effective attenuation coefficient. In assuming that no light will be absorbed per unit path length, the equation reduces to:

$$\text{Depth} = 1 / (\mu_s(1-g))$$

This equation, which is actually the reciprocal of the reduced scattering coefficient, is well-known in the art and it would be obvious to one having ordinary skill in the art to utilize it to estimate a depth traversed by light through a turbid medium.

In Eckhouse, see column 5, lines 40-55.

In Khalil, see column 8, line 56 through column 9, line 7.

Regarding claim 30, as taught by Alfano and Groner, illuminating turbid medium at various depths requires utilizing light pulses of different wavelengths. This is also described within the claim itself. Therefore, this claim is an intended use. Alfano and Groner are capable of performing this function depending on the wavelength and tissue region used.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner et al. and Eckhouse or Khalil, and further in view of Kaufman et al. (US Patent No. 5,971,767). Alfano'394 in combination with Groner and Eckhouse or Khalil is previously described. However, these references do not discuss creating a three-dimensional image. Kaufman states that three dimensional images can be

formed by stacking two-dimensional pictures produced from scanning machines. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a three-dimensional image, as taught by Kaufman, using the methods of Alfano and Groner, because visualizing an organ in three-dimensional space would be beneficial due to its lack of physical intrusion and the ease of data manipulation (column 1, lines 48-51).

Claims 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner, and further in view of Alfano et al.'983 (US Patent No. 6,091,983). Alfano'394 in combination with Groner is previously described. In as much as Groner's described embodiment is for imaging of blood, hemoglobin is used as a natural contrast agent. However, neither of these references describe applying a contrast agent. Alfano'983 teaches a method and system for imaging an object in a turbid medium, but adds a contrast agent to the object to make it luminescent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a contrast agent to the area under examination in order to prevent an object of interest from hiding within the turbid medium (column 3, lines 26-32).

When applying a separate contrast agent, it would be obvious, in light of Groner, for one wavelength to be chosen such that it lies at an absorbing wavelength of the

contrast agent while a second wavelength would be a non-absorbing wavelength for the contrast agent.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner et al. and Alfano'983, and further in view of either Eckhouse et al. (US Patent No. 5,836,999) or Khalil et al. (US Patent No. 6,615,061). Alfano'394 in combination with Groner and Alfano'983 is described above. However, neither of these references discuss a depth estimation. Khalil teaches that the penetration depth is the reciprocal of the effective attenuation coefficient. In assuming that no light will be absorbed per unit path length, the equation reduces to:

$$\text{Depth} = 1 / (\mu_s(1-g))$$

This equation, which is actually the reciprocal of the reduced scattering coefficient, is well-known in the art and it would be obvious to one having ordinary skill in the art to utilize it to estimate a depth traversed by light through a turbid medium.

In Eckhouse, see column 5, lines 40-55.

In Khalil, see column 8, line 56 through column 9, line 7.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner et al. and Alfano'983, and further in view of Kaufman et al. (US Patent No. 5,971,767). Alfano'394 in combination with Groner and Alfano'983 is previously described. However, these references do not discuss creating a three-dimensional image. Kaufman states that three dimensional images can be formed by

stacking two-dimensional pictures produced from scanning machines. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a three-dimensional image, as taught by Kaufman, using the methods of Alfano and Groner, because visualizing an organ in three-dimensional space would be beneficial due to its lack of physical intrusion and the ease of data manipulation (column 1, lines 48-51).

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al.'394 in view of Groner et al. and Alfano'983, and further in view of Richards-Kortum et al. (US Patent No. 6,593,101). Alfano'394 in combination with Groner and Alfano'983 is previously described. However, the specific contrast agents of claim 35 are not taught in these references. Richards-Kortum describes several contrast agents, including toluidine blue, in the abstract. Furthermore, Example 1 (in column 10-11) states that reflected light was used to evaluate backscattering characteristics at wavelengths of 514.5 and 780 nm, which are *about* 390 and 750 nm, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize any contrast agent, including toluidine blue, in order to satisfy the conditions of claim 18 (a) while also taking into account the depth factor that is associated with wavelength, as taught by Alfano'394 and Groner, as a matter of design choice.

Conclusion

Other prior art:

Alfano et al. 6,665,557

Particularly lines 5-11 of the Abstract.

Alfano et al. 5,929,443

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art
Unit 3737

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